510K) SUMMARY K111361

DATE
May 18, 2011

PRODUCT, CLASSIFICATION NAME
Trade name: Planmed Nuance Excel
Common name: Full Field Digital Mammography (FFDM) System
Classification: MUE, Class II
Regulation number: 21 CFR 892.1715

MANUFACTURER
Planmed Oy
Asentajankatu 6
FI-00880 Helsinki, Finland
Phone: +358 20 7795 300
Fax: +358 20 7795 396
Contact person: Lars Moring

UNITED STATES SALES REPRESENTATIVE (U.S. DESIGNATED AGENT)
Planmed USA Inc.
100 North Gary Avenue, Suite A
Roselle, IL 60172
Phone: (630) 894 2200
Fax: (630) 894 4271
Contact person : Bob Pienkowski

INTENDED USE
Planmed Nuance Excel is a FFDM (Full Field Digital Mammography) X-ray unit, which is intended to be used for screening and diagnosis of breast cancer in the same clinical applications as traditional film/screen mammography X-ray units.

The system generates digital mammograms which enable to detect breast cancer at an early stage. The use of Planmed FFDM X-ray unit is allowed only under supervision of a health care professional.

PRODUCT DESCRIPTION
The Planmed Nuance Excel is a Full Field Digital Mammography (FFDM) system for generating mammographic images that can be used for screening and diagnosis of breast cancer. The Planmed Nuance utilizes an amorphous selenium based digital image receptor to capture digital images. The receptor directly converts the incoming X-ray photons to digital image data.

The workflow with Planmed Nuance Excel is controlled from the acquisition workstation and Planmed Nuance Manager 3 image acquisition and communications software. The patient information is entered manually or received from the hospital, radiology, or mammography information systems (HIS, RIS, or MIS, respectively), as a format of modality work list. Subsequently, the images are acquired, processed, and displayed for preview. After initial evaluation by the user, the images are either printed or transferred for soft-copy review.

SUBSTANTIAL EQUIVALENCE

We consider this product modification to be similar in design, composition and function to the following device introduced into commercial distribution after May 28, 1976:

PMA # 030010 Siemens Mammomat Novation DR

The comparison of characteristics supports substantial equivalence. Planmed Nuance Excel is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Planmed Oy
% Mr. Bob Pienkowski
Managing Director, US Agent
Planmed USA, Inc.
100 North Gary Avenue, Suite A
ROSELLE IL 60172

SEP 23 2011

Re: K111361
Trade/Device Name: Planmed Nuance Excel
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: August 8, 2011
Received: August 10, 2011

Dear Mr. Pienkowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111361

Device Name: Planmed Nuance Excel

Indications For Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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